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Joint Program Executive Office for Chemical and Biological Defense Medical Virtual Industry Day

Joint Program Executive Office for Chemical and Biological Defense

Centrally Acting Nerve Agent Treatment Systems (CANATS)

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Disclaimer

- **While we are presenting our currently planned Business Opportunities, we recognize that these may change given our changing fiscal environment and the strategic guidance of the Department of the Defense.**
- **New starts and increases to production levels in FY13 will be delayed until the Appropriations Bill is passed.**

Capability Gap & Product Description

Capability Gap:

Insufficient nerve agent antidotes to preserve neurological function of Warfighters exposed to nerve agents

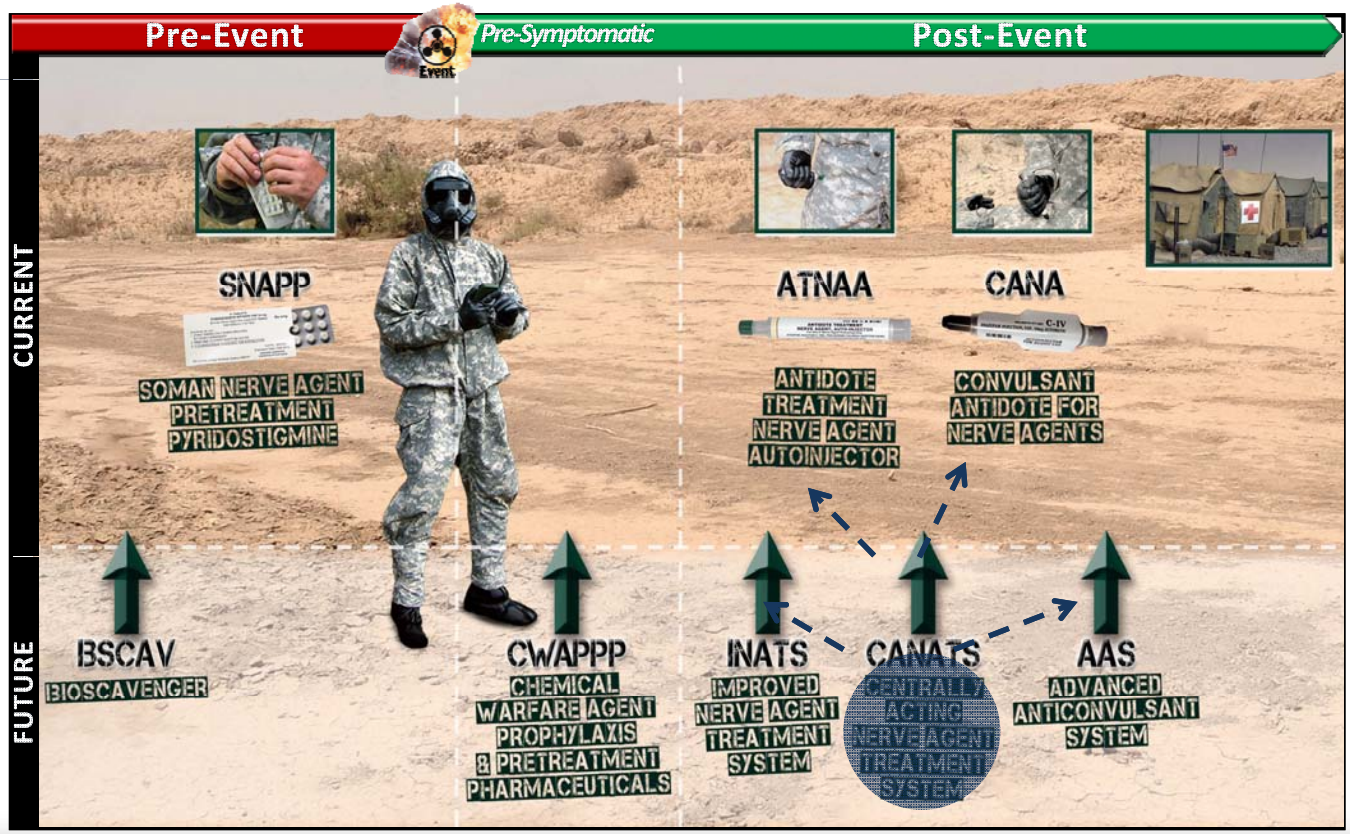
Product Description:

New capability intended to enhance the treatment of severe causalities by rapidly treating the central symptoms (i.e., neurological effects in the brain) of nerve agent intoxication

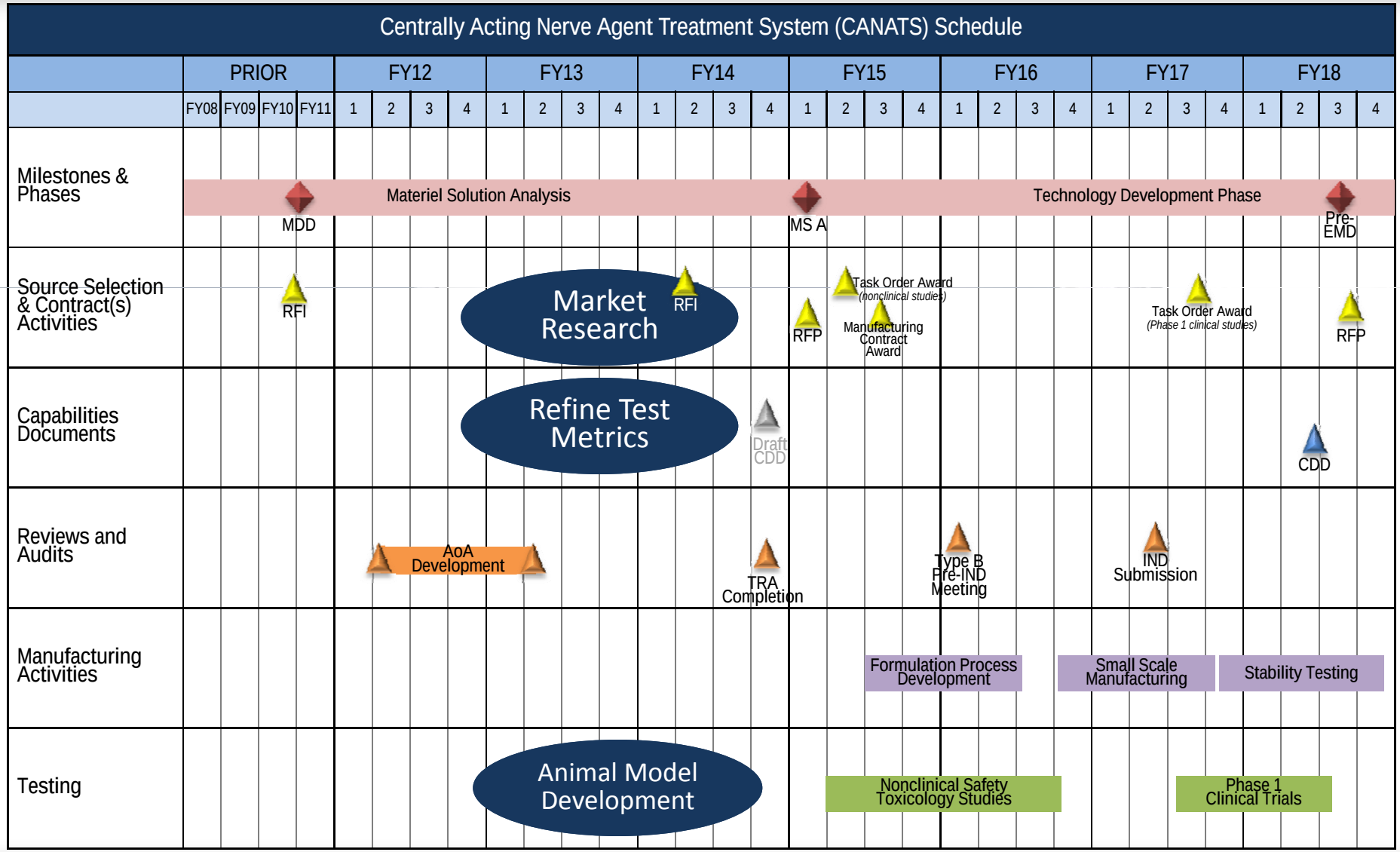
Product is intended as a soldier carried, self/buddy-administered medical countermeasure when given immediately following nerve agent exposure

Product Fit in the Family of Systems

- **Provides additional benefit to address CNS functions, thereby augmenting current therapeutic capability**
- **CANATS will save additional Warfighter lives and decrease performance degradation**



Product Schedule



Acquisition and Contracting Strategy

Anticipated Acquisition Strategy

- A single step acquisition approach to achieve full capability
- CBMS-MITS will develop the CANATS through FDA approval and delivery of a Full Operational Capability (FOC)
- CBMS-MITS as a system integrator through Milestone B
- Current funding supports the development of a single prototype, through Milestone B, assuming a repurposed candidate

Anticipated Contracting Strategy

- Release Request for Information (RFI) 2QFY14
- Release Request for Proposal (RFP) at Milestone A for manufacturing in 1QFY15
- Utilize existing or future Task Order contracts

Technology Gap

- **Insufficient maturity of candidates**
  - Candidate maturity < TRL 4
- **Inadequate animal models available to demonstrate neurological protection**
  - Cognitive and behavioral models are immature
  - Test metrics require refinement and acceptance by regulatory agency

Business Opportunities

- **Broad Agency Announcement: CBMS-BAA-07-01**
  - Category 3 Medical CBRN Countermeasures and Enabling Technologies
  - Category 4 Other

- **Anticipated RFIs (estimated to be released 2QFY14)**
  - Seek industry interest/input on a contract solution for the advanced development, FDA-approval, manufacture, and production
  - Seek information on other centrally-acting therapeutic candidates

Collaboration Partnerships

LEGEND:

- **DTRA/JSTO:** Defense & TecThreat Reduction Agency/ Joint Science hnology Office
- **USAMRICD:** United States Army Medical Research Institute of Chemical Defense
- **BARDA:** Biomedical Advanced Research & Development Authority

DTRA/JSTO

- Integrated product team (IPT) member
- Approved CANATS Capability Transfer Agreement (CTA)
- Approved scopolamine Technology Transfer Agreement (TTA)
- DTRA awarded contracts/grants under BAA to evaluate scopolamine, carisbamate, cobezam, GluR5 kainate receptor antagonists, phenserine, and linolenic acid
- HDTRA1-12-CHEM-BIO-BAA

USAMRICD

- IPT member
- Evaluating survival and improved neuroprotective benefits
- Ability to accept contract work with agent
- Standing up Advanced Development (ADME) Center of Excellence

BARDA

- IPT member
- BARDA awarded contract/grant under BAA to examining galantamine as a potential centrally acting capability for neuroprotection
- BARDA-CBRN-BAA-12-100-SOL-00011

Points of Contact

Learn how we partner with industry, other government agencies and academia.
www.jpeocbd.osd.mil/packs/Default.aspx?pg=1207

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Acronym Glossary

ADM: Acquisition Decision Memorandum or Advanced Development & Manufacturing
AoA: Analysis of Alternatives
APUC: Acquisition Procurement Unit Cost
AS: Acquisition Strategy
BARDA: Biomedical Advanced Research and Development Authority
BBP: Better Buying Power
BLA: Biologics License Application
BSV: Biosurveillance
CBMS: Chemical Biological Medical Systems
CDD: Capability Development Document
CPD: Capability Production Document
cGMP: Current Good Manufacturing Practice
CONOPS: Concept of Operations
CPIF: Cost Plus Incentive Fee
DARPA: Defense Advanced Research Projects Agency
DHS: Department of Homeland Security
DoD: Department of Defense
DSTL: Defense Science Technology Laboratory
DTRA/JSTO: Defense Threat Reduction Agency/Joint Science and Technology Office
EMD: Engineering Manufacturing and Development
EPA: Environmental Protection Agency
FDA: US Food & Drug Administration
FFP: Fixed Firm Price
FOC: Full Operational Capability
FRP: Full Rate Production
FY: Fiscal Year
HHS: Health and Human Services
IBR: Integrated Baseline Review
ICD: Initial Capabilities Document
IND: Investigational New Drug
IOC: Initial Operational Capability
JILA: Joint Integrated Logistics Assessment
JPEO: Joint Program Executive Office(r)
JPM: Joint Project/Product Manager
JPM-ADM: Joint Project Manager- Advanced Development & Manufacturing
JPMO: Joint Project/Product Management Office
JRO-CBRND: Joint Requirements Office for Chemical, Biological, Radiological, and Nuclear Defense
JVAP: Joint Vaccine Acquisition Program
KPP: Key Performance Parameter
KSA: Key System Attribute
LCCE: Life Cycle Cost Estimate
LCMP: Life Cycle Management Plan
LCSP: Life Cycle Sustainment Plan
LRIP: Low Rate Initial Production
MDA: Milestone Decision Authority
MITS: Medical Identification and Treatment Systems
MS: Milestone
MSR: Manufacturing Sustainment Rate
NDA: New Drug Application
NGDS: Next Generation Diagnostic System
NIH: National Institutes of Health
NTA: Non-Traditional Agent
O&M: Operation and Maintenance
OASD (HA): Office of the Assistant Secretary of Defense (Health Affairs)
OGA: Other Government Agency
OSD (NCB/CB): Office of the Secretary of Defense (Nuclear/Chemical Biological)
OSTP: Office of Science and Technology Policy
OUSD(C): Office of the Under Secretary of Defense (Comptroller)
PAIO: Joint CBRN Defense Program Analysis Integration Office
RDT&E: Research, Development, Test and Evaluation
RFP: Request For Proposal
SEP: Systems Engineering Plan
SNS: Strategic National Stockpile
SPA: Special Protocol Assessment
TD: Technology Development
TDP: Technical Data Package
TED: Troop Equivalent Dose
THP: Trained Health Care Provider
TMT: Transformational Medical Technologies
TOA: Total Obligation Authority
TRA: Technology Readiness Assessment
TRL: Technology Readiness Level
USAMMDA: US Army Medical Materiel Development Activity
USAMRIID: US Army Medical Research Institute of Infectious Disease
USAMRICD: US Army Medical Research Institute of Chemical Defense
USAMRMC: US Army Medical Research and Materiel Command